UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/503,852 | 02/15/2000 | Jonathan L. Tilly | 2653/28 | 5439 |

23838 7590 06/30/2005

KENYON & KENYON
1500 K STREET NW
SUITE 700
WASHINGTON, DC 20005

| EXAMINER | |
|---|---|
| SPEAR, JAMES M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1618 | |

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAILED
JUN 30 2005
GROUP 1600

**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 09/503,852
Filing Date: February 15, 2000
Appellant(s): TILLY ET AL.

JOSEPH A. COPPOLA

For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 15 July 2004.

*(1) Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

*(3) Status of Claims*

The statement of the status of the claims contained in the brief is correct.

*(4) Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

*(5) Summary of Invention*

The summary of invention contained in the brief is correct.

*(6) Issues*

The appellant's statement of the issues in the brief is correct.

***(7) Grouping of Claims***

*The claims stand or fall together.*

***(8) Claims Appealed***

The copy of the appealed claims contained in the Appendix to the brief is correct.

***(9) Prior Art of Record***

*Perez et al "Apoptosis-Associated Signaling Pathways Are Required For Chemotherapy-Mediated Female Germ Cell Destruction" Nature Medicine, Volume 3, No. 11 (Nov. 1997), pp 1228-1232.*

| | | |
|---|---|---|
| *5,712,262* | *SPIEGEL* | *1-1998* |
| *5,877,167* | *IGARASHI et al* | *3-1999* |

***(10) Grounds of Rejection***

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 5-12, 17, 18, 20-23, 32 and 74 are rejected under 35 U.S.C. 103(a). This rejection is set forth in a prior Office Action, mailed on 16 December 2003 and Advisory mailed on 22 March 2004.

***(11) Response to Argument***

Applicants state the examiner does not provide an explanation of why methods of treating aging or preventing chemoinvasion would be predictive of success for methods of treating a female reproductive system. The position of this examiner is based on the prior art taken as a whole. The primary reference Perez is directed to female sterility resulting from exposure of oocytes from the reproductive system to doxorubicin, a

chemotherapy drug. While the exposure is in vitro, the conditions for the exposure are made to simulate an in vivo environment as closely as possible. Applicants further state that "Perez contains explicit statements of doubt as to whether Perez's in vitro results with isolated oocytes can be successfully extrapolated to methods of treating the female reproductive system (as opposed to isolated oocytes)". Perez shows what is known in the art, a treatment method directed to the reproductive system of a mammal requiring administration of sphingosine-1-phosphate, the same agent used by applicants. Page 1228. How effective in vivo or whether it is effective in vivo is not considered an issue to be determined by this office. The reference shows what is known in the art. Applicants further state "Spiegel and Igarashi have absolute nothing to do with oocytes or female reproductive systems and thus should not be combined with Perez". " Even if so combined, Spiegel and Igarashi cannot overcome the statements of doubt in Perez as to treating female reproductive system since Spiegel and Igarashi have nothing to do with female reproductive systems". Spiegel teaches the use of sphingosine-1-phosphate to treat degenerative diseases. One species of degenerative disease, neurodegenerative disease, is exemplified. See Abstract, column 1, lines 9-16. Degenerative diseases encompass many diseases, including those that may effect the reproductive system. Igarashi et al teaches the treatment of cells by administering sphingosine-1-phosphate. The treatment is not limited to a particular part of a mammal and therefore encompasses the reproductive system of a female. Both Spiegel, column 2, lines 3-27, and Igarashi et al, column 8, lines 4-20, teach in vivo administration of

sphingosine-1-phosphate to mammals. It is the position of this office that the prior art taken as a whole can and should be combined.

Applicants further state, "It is well settled that a finding of obviousness requires that the cited references provide a reasonable expectation of success for the claimed invention. It is not sufficient that the references make it obvious to try to make the claimed invention." "Perez alone cannot provide a reasonable expectation of success for the claimed invention because Perez is directed to an in vitro method (administering sphingosine-1-phosphate to isolated oocytes) to protect against an in vitro insult (administering doxorubicin to isolated oocytes). While this is true, in medicine virtually all drug therapies initially begin with in vitro studies. Success with in vitro studies would suggest efficacy in vivo. To what degree or what percentage of studies lead to success is not something to easily compare because every drug is different. However it appears Perez et al demonstrates a reasonable expectation of success. While the statements may be optimistic, they do explicitly indicate an expectation of failure.

While Perez et al contains no demonstration of the effects of sphingosine-1-phosphate on follicles, applicants claim 1 is not so limited. Applicants claim 1 is directed to the female reproductive system and therefore encompasses the teaching of Perez et al. Applicants also state, "Spiegel and Igarashi cannot bridge the gap between Perez's in vitro results in oocytes and the Applicants' invention directed to the female

reproductive system because Spiegel and Igarashi have absolute nothing to do with oocytes or female reproduction". As previously stated Perez, Igarashi et al, and Spiegel all teach about an abnormality in relation to cellular function in mammals and the effect of administering sphingosine-1-phosphate. Applicants claims to the female reproductive system encompass cellular function. It is the position of this office that the references can and should be combined.

For the above reasons, it is believed that the rejections should be sustained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James M. Spear

James M Spear
Primary Examiner
Art Unit 1618

June 27, 2005

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

G S Kishore

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600